UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/582,951	07/07/00	PETTIT	G 5379-US

HM22/1205

RICHARD R MYBECK
8010 EAST MORGAN TRAIL
SUITE 10
SCOTTSDALE AZ 85258

EXAMINER	
LUKTON,D	
ART UNIT	**PAPER NUMBER**
1653	3

DATE MAILED: 12/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/582,951	Pettit
Examiner	**Group Art Unit**
David Lukton	1653

☒ Responsive to communication(s) filed on *Jul 27, 2000*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-8* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☑ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Applicants are reminded of the preferred arrangement of the specification:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

- The following section heading is required:

  BRIEF DESCRIPTION OF THE DRAWING(S).

  Preferably, this section heading precedes the "Detailed Description of the Invention"

- It is suggested that the first paragraph on page 1 of the speficiation be moved to a later location.

- **An abstract is required**, and does not appear to have been submitted.

- The specification is objected to. On page 4, line 18, the following is present:

  "are described in copending US applications SN *_____* ".

  If this is to be retained, a serial number will be required.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have provided data showing that compounds (to which the claims are drawn) can inhibit fungal growth *in vitro*. An assertion that such inhibition will occur *in vivo* as well would not be challenged. However, it does not follow that fungal growth inhibition, even *in vivo*, will necessarily be of benefit to the "host". A key issue is that of the relative rate of "inhibition" (by the chemical agent) *versus* rate of propagation (of the fungi). If the fungus is reproducing at a rate of 100 "units" per day in the absence of the dolastatin, and e.g., 98 units per day in its presence, the fungal infection would continue to worsen, and so benefit to the host, if it could be measured at all, would fall well short of the threshold amount required for the inhibition to be considered a therapeutic "treatment". In this vein, there is also the matter of anatomical localization of the fungus versus the chemical agent. If the fungus is eradicated in one tissue, but continues to flourish in another, efficacious

treatment cannot be said to occur. Thus, enablement is lacking for a method of treatment of fungal infections.

In addition to the foregoing, claim 1 is drawn not merely to treatment of a fungal infection, but rather, to treatment of any infection that might have been induced by a fungus. Thus, if a fungal infection were effective to cause a break in the skin, and opportunistic bacteria or viruses invaded as a result, the ensuing bacterial or viral infection would be encompassed by the term "fungi-induced infection". Applicants have not established antibacterial or antiviral efficacy of the compounds (of claim 1).

The following is suggested:

> *A method of inhibiting fungal growth in a host comprising administering to said host a composition comprising an acceptable carrier and an effective amount of a compound selected from the group consisting of ...*

Note that the term "pharmaceutically" has been omitted from this claim. The term "pharmaceutical" carries with it an implied assertion of therapeutic efficacy, which is not in evidence.

*

Claims 1-8 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites the term "ingredient". However, the term *compound* is more precise and more appropriate. The term "ingredient" could refer to a

mixture of any number of compounds; in the present case, only a single pure compound is being used (although in conjunction with a carrier).

- Claim 1 recites a Markush group of structures. The conjunction "and" conventionally precedes the last member of a Markush group. The following is one alternative to the existing language of claim 1:

  A method of ...

  ...effective amount of a compound selected from the group consisting of formulae 1a, 1b, 1c, 1d and 1e, wherein the structures of said formulae are as follows:

- Claim 2 recites that "said fungi is *Cryptococcus*". However, "fungi" is the plural of fungus, so as a grammical matter, it would appear then that the "first person plural" form of the verb "to be" should be used, rather than the current "is".

- Claim 3 recites that the "fungi-induced infections are Cryptococcuses". Thus, this language equates an "infection" with a "Cryptococcus", which is not accurate.

- Claim 4 makes reference to administration of a drug to a "host" by "parenteral means". However, the term "host" is broad, and would include all living organisms: plants, marine organisms, insects, prokaryotes and eukaryotes. Accordingly, clarity would be enhanced if the following intermediate claim were introduced, and claim 4 made dependent on that:

  9. *The method according to claim 3, wherein said host is a mammal.*

The same issue applies to claims 5-9.

- In claim 8, the term "water and oil emulsion" is used. Preferably, hyphens are used as follows: *water-and-oil emulsion.*

- In claim 8, the following is recited:

  "delivered in a carrier comprising a water and oil emulsion, petrolatum, mineral oil a moisturizer, a solubilizer, and fragrance.

  However, this is not proper Markush format. Also, are these ingredients part of, or in addition to, the "carrier" recited in claim 1...?

- Note that any deletions or additions to the text of claim 1 would generate ambiguity with respect to the meaning of the square brackets that are already present in that claim.

- Applicants are advised that, as of November, 2000, NO EXTENSIONS OF TIME ARE PERMITTED to file CORRECTED OR FORMAL DRAWINGS, notwithstanding any indication to the contrary that may be present on the Notice of Allowability.

DAVID LUKTON
PATENT EXAMINER
GROUP 1600

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton [phone number (703)308-3213].

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.